IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGAION	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 4 CASES LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION**	

RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DEFENSE EXPERT SAMANTHA J. PULLIAM, M.D.

INTRODUCTION AND SUMMARY

Plaintiffs' Motion and Memorandum seek to exclude certain testimony and opinions of Dr. Samantha Pulliam, one of the designated experts of Ethicon, Inc.; Ethicon, LLC; and Johnson & Johnson (collectively, "Ethicon"). Specifically, Plaintiffs seek to exclude Dr. Pulliam's opinions regarding: (1) mesh cytotoxicity and degradation, (2) fraying and particle loss, (3) the Instructions for Use accompanying TVT and TVT-O, (4) training and teaching. *See* [ECF No. 3623 ("Motion"), ECF No. 3627, at pp.1-2 "Memo"] Plaintiffs also seek to exclude opinions that Plaintiffs erroneously contend constitute improper legal conclusions. As explained below, the Court should deny Plaintiffs' Motion.

I. Dr. Pulliam is Qualified to Offer the Opinions Offered in Her Report Regarding the Safety and Characteristics of the Mesh Used in TVT and TVT-O.

Plaintiffs seek to exclude Dr. Pulliam's opinions regarding the safety of TVT and TVT-O. Specifically, Plaintiffs argue that Dr. Pulliam "is not qualified to opine that prolene mesh and the TVT device are not cytotoxic[]" because she "is not a toxicologist, and her background is devoid

of *any experience* translating laboratory cytotoxicity test results into clinical effect[;]" she hasn't examined explanted mesh under the microscope; and she has never personally tested mesh. *Id*. at 4-5 (emphasis added). Plaintiffs argue that Dr. Pulliam lacks the requisite qualifications because "her clinical practice is devoid of any experience in cytotoxicity, such as encountering cytotoxicity in her patients or removing mesh implants as a result of cytotoxicity." *Id*. at 6. Similarly, Plaintiffs argue that she is not qualified to offer the degradation opinions set forth in her report, primarily due to her purported failure to conduct specific tests or to perform a sufficient number of explants. *Id*. at 7. Finally, Plaintiffs offer the conclusory argument that Dr. Pulliam is not qualified to offer opinions regarding fraying or particle loss, incorporating, "[f]or the sake of brevity," the arguments regarding her qualifications as they relate to cytotoxicity and degradation.

First and foremost, Plaintiffs gloss over Dr. Pulliam's extensive professional education, training, and experience, erroneously contending that it is "devoid of any experience translating" laboratory results "into clinical effect[.]" *Id*. at 5. As noted in Dr. Pulliam's report, she completed an internship in Anatomic Pathology at Massachusetts General Hospital, which is one of the most reputable teaching hospitals in the United States and the original and largest teaching hospital of Harvard Medical School, thus gaining specialized knowledge and experience "in the basic science of pathology, which [she] ha[s] applied to [her] clinical practice of pelvic reconstructive surgery." Pl. Ex. B, TVT and TVT-O Expert Report of Samantha Pulliam, M.D. ("Pulliam Report") at 2.

More importantly, however, Dr. Pulliam does not seek to opine on what may or may not be demonstrated under a microscope. Her opinions on these materials issues focus upon the *clinical impact* on patients of the use of these materials, which is squarely within her expertise as an experienced pelvic surgeon and is well documented in the medical literature that Dr. Pulliam has reviewed and analyzed.

Plaintiffs also contend that Dr. Pulliam is not qualified to offer the opinion that the mesh used in TVT and TVT-O is not cytotoxic because, in her clinical experience, she has never encountered cytotoxicity as a complication associated with mesh. *See* Memo at 5-6. By that logic, no physician would be qualified to opine that mesh is not cytotoxic because the only person who is qualified is someone who has encountered evidence in their clinical practice suggesting that mesh *is* cytotoxic. This closed, circular and self-serving contention does not demonstrate that Dr. Pulliam is unqualified to opine that the mesh used in TVT and TVT-O is not cytotoxic. It only underscores the need to address Plaintiffs' closed contention with competent expert testimony such as Dr. Pulliam's.

Additionally, an expert is not required personally to perform studies and experiments to opine on a matter. As this Court has found, when an expert relies on scientific literature, as well as her own knowledge and experience, her opinion is considered reliable. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 626 (S.D. W. Va. 2013) (finding an expert's opinion reliable where the expert's report suggested "that he relied not only on his knowledge and experience, but also on scientific literature."). While these matters may be proper for cross-examination, they do not form a basis to exclude her testimony.

Dr. Pulliam's opinions are based upon her experience, as well as her review of clinical studies and medical literature demonstrating the safety and efficacy of TVT and TVT-O, including studies showing "excellent safety, tolerability, low levels of infection," and showing that degradation "does not occur," or that "even if it does, there is no clinically significant impact." Pl. Ex. B, Pulliam Report at 15.

II. Dr. Pulliam's Opinions and Testimony Regarding Cytotoxicity, Degradation, Fraying and Particle Loss are Reliable and Admissible.

In forming the opinions set forth in her report, Dr. Pulliam reviewed and analyzed a significant volume of medical literature. Indeed, she specifically cites to more than 90 articles and/or clinical studies in her report, many of which demonstrate low levels of infection and mesh erosion, supporting her opinions regarding the safety and tolerability of TVT and TVT-O.

However, Plaintiffs also challenge Dr. Pulliam's opinions regarding cytotoxicity, degradation, fraying and particle loss on reliability grounds. Specifically, Plaintiffs argue that Dr. Pulliam's cytotoxicity opinions are unreliable because she failed to specifically identify all of the medical literature upon which she relied in forming her opinions. *See* Memo at 6-7. Similarly, Plaintiffs' reliability challenge with respect to Dr. Pulliam's degradation opinions is based upon purported weaknesses in one of the studies that Dr. Pulliam cites her report. *Id*. at 8-10. Primarily, Plaintiffs contend that a study cited in Dr. Pulliam's report demonstrating "excellent medium and long term results" does not, in fact, provide long-term data. *Id*.

An expert need not identify and explain with particularity each and every study that supports each and every opinion offered. It would be impossible to do so. Whether the particular source is one that experts in the field would routinely rely upon in reaching their opinions is the relevant question, and this ends the inquiry about an expert's reliance upon a particular study in reaching her ultimate conclusions. Dr. Pulliam's opinions are reliable and thus admissible notwithstanding she did not specifically spell out how every study identified in her reliance list supports the opinions offered in her report. For example, Nilsson (2013) reported 17-year data supporting the safety and efficacy of TVT, and Dr. Pulliam read and relied upon the data reported by Nilsson in forming the opinions set forth in her report.

Plaintiffs' arguments go solely to the weight a jury should give Dr. Pulliam's opinions and not the admissibility of such opinions. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 735 (S.D.W.

Va. 2014) (recognizing that expert's failure to review a particular document goes to the weight of the expert's testimony, rather than its admissibility); *see Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *29 (S.D. W. Va. Sept. 29, 2014) ("If the Plaintiffs take issue with Dr. Mays's failure to review or cite particular documents, this goes to the weight of his opinion, not its admissibility, and can be addressed on cross-examination.").

Dr. Pulliam's opinions regarding cytotoxicity, degradation, fraying and particle loss are based upon a combination of her clinical experience and her review of relevant, reliable, Level 1 evidence in the form of clinical studies and published literature. Plaintiffs' arguments go to the weight a jury should afford to Dr. Pulliam's expert testimony -- not to the admissibility of her testimony.

III. Dr. Pulliam's Opinion That Polypropylene Mesh is the Best Material Available for Slings is Reliable and Admissible.

Dr. Pulliam states, in her report, that "To date, polypropylene is the best available material for slings, and has been studied more than any other material used for this purpose." Pl. Ex. B, Pulliam Report at 15. Plaintiffs argue that Dr. Pulliam is "unqualified to render this opinion, but even if qualified, this opinion is unreliable." *See* Memo at 10. As to her qualifications, Plaintiffs essentially argue that only a biomaterials or polymer science expert can offer the opinion that polypropylene has been found to be the "best" material available for slings. *Id.* at 10-12.

However, as set forth above, where an expert's opinion is based, not only upon his or her personal clinical or scientific experience, but also on his or her review of the relevant literature, the opinion is reliable and admissible. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 626. Dr. Pulliam cites to relevant and reliable literature, including Level 1 evidence, supporting her opinion that polypropylene is the most favored and studied material for use in slings to treat stress urinary incontinence. *See* Pl. Ex. B, Pulliam Report at 13-14 (citing Amid (1997) and Ford (2015)).

Again, to the extent Plaintiffs challenge the conclusions of the literature upon which Dr. Pulliam relies, those opinions go to the weight to afford Dr. Pulliam's opinions and testimony, and such arguments are proper subjects of cross-examination. However, Plaintiffs' arguments do not establish that Dr. Pulliam's opinion is unreliable and inadmissible.

IV. Dr. Pulliam's Opinions Regarding the Product IFUs are Reliable and Admissible.

Plaintiffs argue that Dr. Pulliam's opinions and testimony regarding the IFUs for TVT and TVT-O should be excluded because she is not qualified to offer her opinions, and because the opinions are unreliable. *See* Memo at 14-15. Plaintiffs argue that, even if Dr. Pulliam is qualified to offer opinions regarding the product IFUs, such opinions are "riddled with legal conclusions" and, as such, should be excluded. *Id*. at 15.

Once again, Plaintiffs misunderstand the scope of the opinions offered. Dr. Pulliam does not, as Plaintiffs suggest, examine the text of each IFU and offer the "legal conclusion" that such warnings are legally adequate. Rather, Dr. Pulliam offered the opinion that the risks associated with TVT and TVT-O are identified in the product IFUs and/or are commonly known by pelvic floor surgeons, and that it is "incumbent upon surgeons to understand the risks of the procedures they perform, including the risks of the instruments used in the surgery, and the risks of any implants such as polypropylene mesh." Pl. Ex. B, Pulliam Report at 26-27. Dr. Pulliam identifies a federal regulation, which she opines supports the opinion set forth in her report. She does not, as Plaintiffs suggest, opine that because Ethicon's warnings satisfy said regulation, such warnings are adequate.

Dr. Pulliam is qualified by her knowledge, skill, education, training, and clinical experience, as well as her review of medical literature, to opine as to how physicians utilize product IFUs in their clinical practice; what information a physician expects to be included in product IFUs

to enable him or her to safely utilize the product; and what risks associated with the use of TVT and/or TVT-O are generally known by pelvic floor surgeons as compared to those risks that she would rely upon an IFU to identify.

As such, her opinions regarding the product IFUs, as set forth in her report, are reliable and helpful to the jury.

V. Dr. Pulliam's Opinions Regarding Training are Reliable and Helpful to the Jury.

Plaintiffs argue that Dr. Pulliam "is not qualified to render" opinions "regarding training and teaching" because she "has never attended or proctored an Ethicon training session for TVT or TVT-O." Memo at 16. Plaintiffs also argue that these opinions are unreliable "because Dr. Pulliam relies upon the MAUDE database as an 'attest[ation] to the adequacy of training of physicians who perform slings.'" *Id*. at 18.

However, Plaintiffs mischaracterize and/or overstate the scope of Dr. Pulliam's opinions regarding training. The portion of Dr. Pulliam's report discussing Ethicon training supplements and is a continuation of Dr. Pulliam's opinions with respect to the product IFUs. In the section of her report discussing the product IFUs, Dr. Pulliam explains that, in clinical practice, a physician does not rely upon a product IFU as the sole source of information as to how to perform a particular procedure. Indeed, Dr. Pulliam points out, there are many sources from which physicians can gain knowledge regarding certain products and procedures, as well as the risks and complications associated with such procedures.

For example, Dr. Pulliam explains that physicians "attend conferences, training courses, review current medical literature and may undergo surgical proctoring by experts[.]" Pl. Ex. B, Pulliam Report at 26. "Pelvic floor surgeons are thus trained [o]n an ongoing basis to understand the risks, both common and rare, of the surgeries they perform." *Id*. Then, Dr. Pulliam reiterates

that physician training offered by medical device manufacturers, including Ethicon, serves as an additional source to "supplement the surgeon's training and knowledge[.]" *Id*. at 27. Thereafter, Dr. Pulliam generally describes the information taught to or received by physicians attending such training. This description comes from a combination of Dr. Pulliam's experience attending such trainings generally—whether or not sponsored by Ethicon—as well as her review of training materials provided by Ethicon. Pl. Ex. D, Pulliam Dep. Tr. at 248:23-249:21.

Finally, although Plaintiffs contend that Dr. Pulliam's opinions regarding Ethicon training are unreliable because she "relies on" the MAUDE database, *see* Memo at 18, Plaintiffs understate and thus misapprehend the scope of Dr. Pulliam's opinions and ignore additional bases and support for such opinions. Specifically, Dr. Pulliam mentioned the MAUDE database as *a* source of support for her opinions—not the *sole* or even primary source. Rather, Dr. Pulliam specifically stated that she also relied upon the Ford Cochrane review as evidence demonstrating the "adequacy of training of physicians who perform slings[]" generally. Ex. D, Pulliam Dep. Tr. at 250:9-22.

Simply put, Dr. Pulliam is qualified—by education, skill, experience, training, and her review of medical literature and professional education materials—to offer the opinions set forth in her report regarding product warnings and training. Additionally, Dr. Pulliam's opinions are reliable, as it is clear that such opinions are based upon Dr. Pulliam's education, skill, training, clinical experience, and review of medical literature and professional education materials. As such, Plaintiffs' Motion should be denied.

VI. Dr. Pulliam's Opinions Do Not Constitute Improper Legal Conclusions.

Finally, Plaintiffs argue that "Dr. Pulliam offered legal conclusions, such as '[t]hese guidelines and position statements . . . *do not support the idea that TVT/TVT-O is unreasonably dangerous* for its intended use." *See* Memo at 20 (emphasis in original).

With respect, Plaintiffs are improperly and erroneously trying to put words in Dr. Pulliam's mouth and unasserted opinions in her Report. In further support of the opinions offered throughout her report, which were based upon and supported by her clinical experience and review of relevant and reliable scientific literature, Dr. Pulliam cited to industry guidelines and standards that entirely belie and refute Plaintiffs' experts' opinions that TVT and TVT-O are unsafe due to defects in the design of the products.

As such, the statement(s) identified by Plaintiffs do(es) not constitute an improper legal conclusion, and any challenges to the substance of such statement(s) go to the weight of such statements, and not to their admissibility.

CONCLUSION

For these reasons, the Court should deny Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Samantha J. Pulliam, M.D.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 27, 2017, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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